K012461 p. 1/3

AUG 1 7 2001

## 510(k) SUMMARY

as required per 807.92(c)

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: Connie Hertel, Director, QA/RA
Contact person for this submission: Penelope H. Greco
Date submission was prepared: May 25, 2001

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY MIB II Duo Protocol Converter

B. Common Name, Classification Name, Class and Regulation Number:

| Common Name | Product Code | Class | Regulation Number |
|---|---|---|---|
| Transducer Signal amplifier and conditioner | DRQ | II | 21 CFR 870.2060 |

Legally Marketed Device Identification:

Siemens INFINITY MIB II Protocol Converter: 510(k) K010640
Siemens Medical Information Bus (MIB) Protocol Converter:
510(k) K970368, K973222, K991661, K003248

Description of Modification:

The new INFINITY MIB II Duo Protocol Converter employs the same fundamental scientific technology and has the same intended use as that of the predicate device. The INFINITY MIB II Duo Protocol Converter supports the same devices and device specific cables as that of the predicate device, 510(k) K010640. Siemens original MIB Protocol Converter (K970368, K973222, K991661, K003248) uses SDL style connectors. The MIB II (K010640) uses RJ45 connectors. Modifications have been implemented to enable use of both connector types. The INFINITY MIB II Duo Protocol Converter supports IEEE Standards 1073.3.1 (Medical Device Communications-Transport Profile-Connection Mode) and 1073.3.2-2000 (Medical Communications – Transport Profile – IrDA Based – Cable Connected).

The only difference between the INFINITY MIB II and INFINITY MIB II Duo Protocol Converter is that the "Duo" has an additional interface and is compatible with the IEEE Standard 1073.3.1. No other modifications were required to implement this change. Testing has been performed to validate the overall performance of the modified MIB II Duo Protocol Converter and to verify proper communication with the INFINITY modular bedside monitors and the MIB supported devices.

Electromagnetic compatibility testing has been performed by Chomerics Test Services in accordance with EN 60601-1-2, Part 2, Medical Electrical Equipment Collateral Standard: Electromagnetic compatibility, and in accordance with FDA suggestions.





**Siemens Medical Systems, Inc.**
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
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Intended Use:
The INFINITY MIB II Duo Protocol Converter is intended for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that a third party medical device should be connected to Siemens INFINITY Modular Monitors (SC 7000 / SC 8000 / SC 9000 / SC 9000XL) for display of data from devices such as:

- Siemens SV 300 ventilator
- Baxter Vigilance blood gas/continuous cardiac output monitor
- Siemens SV900 ventilator
- Draeger Evita II ventilator
- Draeger Evita IV ventilator
- Draeger Babylog ventilator
- Puritan Bennett 7200 ventilator
- Draeger Narkomed II Anesthesia System
- Draeger Narkomed IV Anesthesia System
- Draeger Julian Anesthesia Machine
- Ohmeda 7900 Anesthesia Machine
- Abbott Oximetrix 3 Blood Gas Analyzer
- AVL Medical Instruments: Opti Critical Care Analyzer Portable Blood Gas Analyzer
- Optical Sensors Inc.: OSI – Optical CAM
- VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
- Aspect A-2000 BIS Monitor*

*The SC 9000 does not support communication with the Aspect BIS Monitor

Assessment of non-clinical performance data for equivalence: Section J

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances:
1073.3.1 Medical Device Communications-Transport Profile-Connection Mode
1073.3.2 – 2000 IEEE Standard for Medical Communications
Transport Profile – IrDA Based – Cable Connected



**COMPANY CONFIDENTIAL**

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## Premarket Notification
## Truthful and Accurate Statement
(As required per 21 CFR 807.87[j])

I certify, in my capacity as Director of Quality Assurance and Regulatory Affairs of Siemens Medical Systems, Inc., Electromedical Systems Group, PCS, that I believe, to the best of my knowledge, that all data and information submitted in this premarket notification to be truthful and accurate and that no material fact has been omitted.

Linda Adamson proxy for Connie Hertel 7/31/01

Connie Hertel, Director — Date
Quality Assurance & Regulatory Affairs
Official Correspondent

_____
[Premarket Notification 510(k) Number]



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 7 2001

Ms. Penelope H. Greco
Siemens Medical Systems, inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K012461
Trade Name: INFINITY MIB II Duo Converter
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: July 31, 2001
Received: August 1, 2001

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indicated Use Statement



510(k) Number (if known): K012461

Device Name: Siemens INFINITY MIB II Duo Protocol Converter

Indications for Use:

Siemens INFINITY MIB II Duo Protocol Converter is indicated for use in an environment where patient care is provided by healthcare professionals (Physician, Nurse, Technician) when the professional determines that third party devices that do not provide data per the IEEE 1073 Medical Information Protocol Standard should be connected to a Siemens INFINITY Modular Monitor (SC 9000 / SC 7000 / SC 8000 / SC 9000XL) for the display of data. MIB connectivity to third party medical devices such as:

Siemens SV 300 ventilator
Baxter Vigilance blood gas/continuous cardiac output monitor
Siemens SV900 ventilator
Draeger Evita II ventilator
Draeger Evita IV ventilator
Draeger Babylog ventilator
Puritan Bennett 7200 ventilator
Draeger Narkomed II Anesthesia System
Draeger Narkomed IV Anesthesia System
Draeger Julian Anesthesia Machine
Ohmeda 7900 Anesthesia Machine
Abbott Oximetrix 3 Blood Gas Analyzer
AVL Medical Instruments: Opti Critical Care Analyzer, Portable Blood Gas Analyzer
Optical Sensors Inc.: OSI – Optical CAM
VIA Medical: VIA V-ABG1 Blood Gas Chemistry Monitor
*Aspect A-2000 BIS Monitor

*The SC 9000 does not support communication with the Aspect BIS Monitor

**MRI Compatibility Statement:**
The INFINITY MIB II Duo Protocol Converter is not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012461